

4742. Nu Youth tablets. (F. D. C. No. 36655. S. Nos. 40-225 L, 58-142 L.)

INFORMATION FILED: 7-28-55, S. Dist. Calif., against Frederic S. Weichman, t/a N-Y Distributing Co., Los Angeles, Calif.

SHIPPED: 1-15-54 and 1-20-54, from California to Arizona and Illinois.

LABEL IN PART: (Btl.) "Each tablet contains 5 mg. Methylandrostenediol suggested dosage. One tablet upon arising before breakfast and one tablet shortly before retiring. For adult males not for children or young adults Caution: Do not take more than dosage recommended. Continued use extending over six months to be avoided, except under supervision of a physician. Do not use in cases of cardiac and kidney disease, cancer of the prostate, defects of spermatogenesis, sterility or debilitation due to disease. Indications: Used in place of testosterone, methyltestosterone and testosterone propionate for its androgenic effect and as an anabolic agent * * * Nu Youth 60 Tablets."

ACCOMPANYING LABELING: Leaflets entitled "The Evidence" and undated letters addressed to "My Dear Friend" and signed by "Charles St. Regis" under the letterhead of N-Y Distributing Co.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the drug was a new, improved, safe sex hormone; that it could be used in place of testosterone, methyltestosterone, and testosterone propionate for its androgenic effect; and that it would be adequate and effective for providing renewed vigor, endurance, strength, and vitality in men over 40; for rejuvenating men by replenishing their deficient sex glands; for restoring masculine sex drive; for banishing mental fatigue; for boosting muscle power; for replenishing energy and endurance; for increasing mental alertness and ending irritability; for providing health, sexual aliveness, and emotional stability; for sex problems and impotency; for restoring waning physical and mental powers in men; for providing pep and vitality; and for providing the proper functioning and well-being of the human body; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use; 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration recommended in its labeling; 503 (b) (1)—the article was dispensed without a prescription therefor from a practitioner licensed by law to administer the drug; and 503 (b) (4)—the article was subject to 503 (b) (1), and at a time prior to dispensing, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Guilty.

DISPOSITION: 9-26-55. \$200 fine.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4743. Achromycin capsules. (F. D. C. No. 37701. S. No. 12-707 M.)

QUANTITY: 52 100-capsule btls. at West Orange, N. J.

SHIPPED: During January 1955, from Bronx, N. Y., by Al Getzoff, t/a Re Ly On Drug Co.

LABEL IN PART: (Btl.) "Stellar Drug Company Wholesale Druggists 32 West 15th Street New York 11, N. Y. (100) Achromycin Capsules 250 mg. repacked (Lederle) #4768 Nov. 1956."

LIBELED: 3-8-55, Dist. N. J.

CHARGE: 502 (e) (2)—the label of the article when shipped failed to bear the common or usual name of the active ingredient, tetracycline; 502 (f) (1)—the labeling of the article failed to bear the information required by regulations